UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,161	01/30/2002	Ayako Toda	218975US0PCT	1456

22850 7590 06/16/2004

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,161	TODA ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/30/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The Information Disclosure Statements filed April 3 and December 5, 2003 are acknowledged, in which related applications 09/926,385 and 10/469,233 are listed. However, application 10/469,233 is not available for viewing at this time, thus it is not considered.

Claim Objections

2. Claim 2 is objected to because of the use of the term "A compound of claim 1". Since claim 2 is dependent from claim 1, the term "The compound of claim 1" should be used. See also claims 3-10.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of co-pending application 09/926,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-10 in the instant application disclose

a polypeptide compound of formula (I), wherein R^1 is hydrogen or acyl group, R^2 is hydrogen or acyl group, R^3 is lower alkyl which has one or more hydroxy or protected hydroxy, R^4 is hydrogen or hydroxy, R^5 is hydrogen, hydroxy, lower alkoxy or hydroxysulfonyloxy, and R^6 is hydroxy or acyloxy, or a salt thereof; a process for preparing the compound of formula (I) or a salt thereof; a pharmaceutical composition comprising the compound of formula (I) or a salt thereof, and a pharmaceutically carrier; use of the compound of formula (I) or a salt thereof for the manufacture of a medicament; and a method for prophylactic or therapeutic treatment of infectious diseases caused by pathogenic microorganisms, comprising administering the compound of formula (I) or a salt thereof to a human being or an animal. This is obvious in view of claims 1-12 of the copending application which disclose a polypeptide compound of formula (I), wherein R^1 is hydrogen or acyl group, R^2 and R^3 are independently hydrogen, lower alkyl which may have one or more suitable substituent(s), acyl group or other cited group, R^4 is hydrogen or hydroxy, R^5 is hydrogen, hydroxy, lower alkoxy or hydroxysulfonyloxy, and R^6 is hydroxy or acyloxy, or a salt thereof; a process for preparing the compound of formula (I) or a salt thereof; a pharmaceutical composition comprising the compound of formula (I) or a salt thereof, and a pharmaceutically carrier; use of the compound of formula (I) or a salt thereof for the manufacture of a medicament; and a method for prophylactic or therapeutic treatment of infectious diseases caused by pathogenic microorganisms, comprising administering the compound of formula (I) or a salt thereof to a human being or an animal. Both sets of claims are directed to a polypeptide compound of formula (I), wherein R^1, R^4, $R^5$and R^6 are independently defined as above, and wherein R^2 can be hydrogen or acyl group, and R^3 can be lower alkyl which has one or more suitable

substituent(s) such as hydroxy, or a salt thereof; a process for preparing the compound of formula (I) or a salt thereof; a pharmaceutical composition comprising the compound of formula (I) or a salt thereof; use of the compound of formula (I) or a salt thereof for the manufacture of a medicament; and a method for prophylactic or therapeutic treatment of infectious diseases by administering the compound of formula (I) or a salt thereof to a human being or an animal. Therefore, claims 1-10 in the instant application and claims 1-12 of the co-pending application 09/926,385 are obvious variations of a polypeptide compound of formula (I), wherein R^1 is hydrogen or acyl group, R^2 is hydrogen or acyl group, R^3 is lower alkyl which has one or more hydroxy or protected hydroxy, R^4 is hydrogen or hydroxy, R^5 is hydrogen, hydroxy, lower alkoxy or hydroxysulfonyloxy, and R^6 is hydroxy or acyloxy, or a salt thereof; a process for preparing the compound of formula (I) or a salt thereof; a pharmaceutical composition comprising the compound of formula (I) or a salt thereof; use of the compound of formula (I) or a salt thereof for the manufacture of a medicament; and a method for prophylactic or therapeutic treatment of infectious diseases by administering the compound of formula (I) or a salt thereof to a human being or an animal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Restriction in copending application 09/926,385 between product and process of making as well as product and process of using is acknowledged. However, that restriction has not been final. Given the 371 status of the instant and copending applications, the Obviousness Type Double Patenting set forth presently is deemed proper.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a method of prophylactic or therapeutic treatment of infectious diseases caused by pathogenic microorganisms, comprising administering the compound of formula (I) to a human being or an animal (claim 10); use of the compound for the manufacture of a medicament (claim 8); and, a commercial package or an article of manufacture comprising a pharmaceutical composition of the compound (I) or the

compound (I) and a written matter, wherein the written matter indicates the pharmaceutical composition or the compound (I) can be or should be used for preventing or treating infectious disease (claims 11 and 12). The specification indicates four examples of compound (I) are tested in mouse serum against a specific microorganism (candida albicans) and show antimicrobial activity *in vitro* (page 30, line 25-page 31, line 14), and it also states the compound (I) has antifungal activity against various fungi, which are known to cause various infectious diseases, thus the compounds (I) are useful for preventing and treating various infectious diseases (pages 31-33). The specification further asserts a therapeutically effective amount of compound (I), which depends on the age and condition of individual patient, can be administered via different route in general terms (pages 34-35); and the written material in the commercial package or in the article of manufacture indicates the compound (I) can or should be used for preventing or treating infectious diseases (page 35, line 35-page 36, line 15). However, the specification has not described how to prophylactically treat a specific infectious disease using an example of compound (I) *in vivo*, nor has demonstrated the effect of the compound (I) in the treatment, e.g., administering an effective amount of the peptide to produce a desired outcome of the treatment. Although the specification has shown antimicrobial activity of certain compounds of formula (I) *in vitro*, it does not teach how to extrapolate the *in vitro* data to *in vivo* effect. Moreover, the specification does not indicate the written material in commercial package or article of manufacture describes how to use the compound (I) (e.g., dosage) for effective prevention or treatment of various infectious diseases, and how to manufacture a medicament using compound (I). The lack of description of the use and the effect of compound (I) in prophylactic and

therapeutic treatment of various infectious diseases, in commercial package or article of manufacture, and in the manufacture of a medicament as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 6 is indefinite because of the use of the term "reactive derivative at the amino group". The term "reactive derivative at the amino group" renders the claim indefinite, it is unclear what structure the derivative has, and how different the derivative is from the parent compound since neither the claim nor the specification has defined the term.

8. Claim 8 provides for the use of the compound of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

9. Claim 9 is indefinite because the claim has the same scope as independent claim, claim 1. The term "for use as medicament" is intended use, which does not have weight in the product claim.

10. Claim 10 is indefinite because the claim lacks essential steps in the method of treating infectious diseases. The omitted steps are the amount of the compound of formula (I) administered, and the outcome of the treatment. Claim 10 is also indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and".

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

***

June 13, 2004